## EXHIBIT 220



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April 25, 2008

Sarita Thapar, PharmD. Director, US Medical Affairs **ACTAVIS LLC** 200 Elmora Avenue Elizabeth, NJ 07207

Sent via Federal Express Overnight - Tracking #791053281809

Re: Health Hazard Evaluations

Dear Sarita:

Please find enclosed the HHE's that you have Dr. Leikin review. As we discussed the is still being typed up and yet to be sent for signature by your office.

If you should have any questions please do not hesitate to contact our office.

Sincerely,

Julie Licata

Administrative Assistant to Jerrold B. Leikin MD

**Director of Medical Toxicology** 

Evanston Northwestern Healthcare - OMEGA

**Enclosures** 

PLAINTIFF'S **EXHIBIT** 

Evanston Hospital Glenbrook Hospital Highland Park Hospital ENH Medical Group

ENH Foundation

ENH Research Institute



Memo
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То	File	Date	18-Apr-08
From	Jerrold B. Leikin MD –Director of Medical Toxicology ENH OMEGA		
Subject	Health Hazard Evaluation – Digoxin Tabs 0.125 mg	Reference	Investigation log # 07- 093

Actavis Medical Affairs contracted Jerrold B. Leikin MD. to perform a Health Hazard Evaluation (HHE) for the subject drug product. Specifically, to evaluate the impact of Digoxin Tabs 0.125 mg that were had a thickness approximately double to that required; this issue was found during packaging/filling operations on packaging line # 405 in November, 2007 (batch # 70924A1).

Therapeutic use: Cardiac inotropic and anti-arrhythmic agent indicated for the treatment of mild to moderate heart failure.

Root cause evaluation noted that the tablets found with double thickness might have been produced during the readjustment at start up. It was believed possible that the tablets might have been stuck in the tablet de-duster or metal detector and was not noticed by the press operator.

Clinical conclusion: Potential risks to the patient depend upon the constituency of the tablets. If the tablets contain double the dose (0.250 mg), then it can be expected that digitalis toxicity can occur in individuals taking daily doses or in patients with renal insufficiency. Toxicity can include nausea, vomiting, dizziness, low blood pressure, cardiac instability and bradycardia. Death can result from excessive digitalis intake.

If the increased thickness is due to clinically inert substances, then a decreased amount of digitalis may be absorbed, leading to exacerbation of the underlying cardiac disease (congestive heart failure and arrhythmia) due to lack of therapeutic efficacy.

Based upon US Actavis Medical Affairs' internal review of domestic spontaneously reported adverse events for the time period of January 1, 2005 until March 31, 2008, a pattern of events were not identified for this product related or unrelated to known adverse events. Serious adverse events implies that such events are associated with death, a life-threatening event, caused permanent disability or damage, led to hospitalization, involved a congenital abnormality, or may have caused an important medical event. In this review, eleven adverse events were noted. Reported adverse event cases do not imply a direct cause-effect relationship of the product and the event since these are spontaneously reported cases that may have multiple confounding factors reported by known and unknown qualified sources.

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Dates : 1	ID Number	Expedited/Periodic	Adverse Event	Domestica de Spontaneous
				(lotinumber and: Exp date)
26-MAY-2006	2006AL001331	PERIODIC	Vision blurred	unknown
05-JUL-2006	2006AL001672	PERIODIC	Rash, Pruritus	unknown
03-AUG-2006	2006AL002107	PERIODIC	Diarrhoea, Fluid retention	unknown
11-SEP-2006	2006AL002747	PERIODIC	Blood pressure increased	unknown
29-SEP-2006	2006AL002987	EXPEDITED	Cardiac failure acute, Cardiac failure congestive	unknown
16-OCT-2006	2006AL003173	EXPEDITED	Tremor, Gait abnormal,	unknown



			Paraesthesia	
05-MAR-2007	2007AL000909	PERIODIC	Drug ineffective,	60400A1
			Dysgeusia, Atrial	
			fibrillation	
10-MAY-2007	2007AL001896	PERIODIC	Hyperaesthesia,	unknown
			Burning sensation,	
			Erythema, Cough,	
			Hoarseness	
01-JUN-2007	2007AL002191	PERIODIC	Asthenia, Fatigue,	unknown
			Visual disturbance	
10-JAN-2008	2008AL000238	PERIODIC	Medication error	unknown
20-MAR-2008	2008AL001820	PERIODIC	Heart rate increased,	unknown
			Drug ineffective	

Jerrold B. Leikin MD, Director of Medical Toxicology ENH OMEGA

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Jasmine Shah, Vice President, US Regulatory Affairs Phyllis Lambridis, Vice President, US Quality & Compliance Tony Delicato, Site Director, Quality Assurance Sarita Thapar, Director of Medical Affairs